

er to discuss the criteria and primary stages necessary for the eventual validation, regulatory acceptance, and implementation of test methods."

Workshop participants sought to identify more efficient ways for developers to communicate information and gain acceptance of their new test methods by scientists in various regulatory agencies without having to systematically approach each agency. For instance, a test method to be used commercially might be of interest to the EPA, the Consumer Product Safety Commission, the DOT, and OSHA. On the other hand, a new test method for a drug may be important to the FDA, but of no interest to any other agency. A question posed at the meeting was how communications between stakeholders might be streamlined to facilitate the review and acceptance process.

Participants at the workshop breakout session on future directions proposed the creation of a clearinghouse through which a developer could bring a new test method to the attention of the appropriate federal regulatory agency or agencies. The clearinghouse was envisioned as an interagency coordinating committee that would facilitate communication between test method developers and agency scientists regarding new alternative test methods for various endpoints. However, at what point in the development and validation process should communications be made with the clearinghouse? After a method has been developed and a validation study designed, consultation with the clearinghouse might determine that the design will not generate sufficient data to be adequately evaluated by regulatory agencies. However, if the data are not communicated until after validation—an expensive procedure—there are inadequate data to evaluate the usefulness of the method by the intended regulatory agencies, and much time and money may have been wasted. The breakout group concluded that a process was needed to facilitate communications among all stakeholders at all stages of development, validation, and acceptance. Oliver Flint, a principal scientist at Bristol-Myers Squibb and executive secretary of the breakout session, supports the idea of a clearinghouse. Said Flint, "From the scientist's point of view, this will have the advantage that individual tests will not have to be revalidated for each regulatory agency; and from the public's point of view, that one agency will not have lower or eccentrically different standards from those of another."

The breakout panel suggested interposing a stage called prevalidation between the

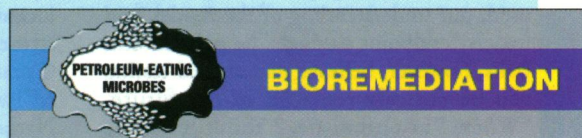
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Reliance on petroleum comes with a price. Because of spills, such as the *Exxon Valdez*, and the numerous barrels of oil that leak from petroleum pipelines, cleaning up petroleum-polluted water and soil is big business. The most common mechanical remediation techniques involve drumming, transportation, and remote disposal of contaminated soil and water to special dump sites and treatment plants.

Recently, an alternative technique called bioremediation has been developed. Bioremediation is the process of using a mix of living microorganisms, nutrients, and biological catalysts to rapidly break down hydrocarbons in soil or water into nonhazardous, nonregulated, organic fertilizer-like compounds. Bioremediation methods are estimated to be five to ten times less expensive than mechanical methods of remediation.

A World Wide Web site dedicated to bioremediation is located at URL: <http://tiger.jvnc.net/~levins/microbes.html#top>. This site was created by Oettco Products Corporation, a company specializing in petroleum-oxidizing products. The site provides an overall explanation of bioremediation methods, materials, and techniques that have been used by professional bioremediation contractors over the last fifteen years. The topics outlined include basic concepts, typical commercial bioremediation materials, the bioremediation industry, safety issues, soil remediation topics, eliminating absorbed petroleum, cleaning coastal soil, and oil slicks on open water.

Bioremediation is not only used to clean up petroleum spills, but is also used to support basic sanitation infrastructures. Algae have been used to treat waste water for over a century, but only recently have certain algae species been actively cultivated to "digest waste." These methods are cost effective and produce little waste, as the leftover algae can be dried and used as fertilizer. Bioremediation methodology and techniques may provide a more environmentally sound way to help clean up the environment.



stages of development and validation. Prevalidation would generate enough data for clearinghouse scientists to assess the likelihood that the test method would pass regulatory testing purposes. A negative finding would stop the process. A positive finding would justify the allocation of additional time and funds for validation, peer review, and hopefully, implementation. The clearinghouse might even assist in identifying potential funding sources.

As discussed by the breakout group, the clearinghouse would communicate information about test methods, not products, and would have only an advisory function to the participating agencies. Its membership would include scientists from all of the relevant federal agencies. Several questions remained, however, such as whether the clearinghouse would be a revamped ICCVAM or a new interagency coordinating committee, how the clearinghouse would be funded, and whether it would eventually be set up to communicate information efficiently to foreign and international regulatory bodies.

ICCVAM co-chairperson William Stokes, associate director of Animal and

Alternative Resources at the NIEHS, agrees with the concepts of the clearinghouse and prevalidation and thinks it would be useful. "Fifteen agencies have worked well together in the ICCVAM to develop the draft report so the proposed clearinghouse functions could be the logical next step. It could have representatives from each [ICCVAM member] agency and 'go international' down the road. Proposals for enhanced international coordination at all stages of validation and acceptance are more likely to emerge at the OECD workshop, where the ICCVAM draft report and workshop report will serve as working documents. The aim is to harmonize our report with that of an OECD guidance document to be developed in Stockholm."

Some workshop participants would like to see animal tests phased out entirely and as soon as possible. For instance, Michael Balls, director of the European Center for the Validation of Alternative Methods, of the European Union Joint Research Center's Environment Institute, called for greater efforts to find replacements for all animal tests as soon as possible.

Many scientists at the meeting ex-